

REMARKS/ARGUMENTS

I. Status of the Claims

Claims 1-9 are pending. Claim 4 is cancelled without prejudice or disclaimer of the substantive matter therein and retaining the right to prosecute in a future continuation application. Claim 1 has been amended and claims 10 and 11 have been added. Support for these amendments and new claims can be found in, for example, p. 2, paragraph 20, and p.6, paragraph 112.

Reconsideration of the pending claims in view of the following remarks is respectfully requested. No new matter is added by way of the present amendments.

II. Rejections under 35. U.S.C. § 112

Claims 1-9 are rejected under 35 U.S.C. § 112 as based on a disclosure which is not enabling. Specifically the Examiner contends that without (1) a stated ratio between the polymer and plasticizer and (2) a specified plasticizer, the claims are not enabled. Claim 4 has been canceled rendering the Examiner's rejection moot.

The claims have been amended to include a ratio between the plasticizer and lactic acid. It should be noted that the ratio used in the examples of Applicant's specification of Example 1, Example 2, Example 3, correspond to the ratio in newly amended claim 1. In regards to the Examiner's rejection based on the lack of stated ratio, it is asserted that these amendments obviate the rejections and therefore the Examiner's rejections should be withdrawn. For these reasons, Applicant respectfully request reconsideration of the above claims.

With regards to the objection of the plasticizer, Applicant respectfully traverses the objection.

As set forth below, one of ordinary skill in the art could practice the invention without undue experimentation.

To be enabling, the specification must teach one of ordinary skill in the art to make and use the full scope of the claimed invention without "undue experimentation." *In re Wright*, 999 F.2d 1557, 1561, 27 U.S.P.Q.2d 1510, 1513 (Fed. Cir. 1993). As long as "undue experimentation" is not involved, a specification complies with the enablement requirement, even if a reasonable amount of routine experimentation is required to

practice the invention. *Enzo Biochem Inc. v. Calgene*, 188 F.3d 1362, 1371, 52 U.S.P.Q.2d 1129, 1135 (Fed. Cir. 1999). Even “a considerable amount of experimentation is permissible, if it is merely routine.” *In re Wands*, 858 F.2d 731, 737, 8 U.S.P.Q.2d 1400, 1404 (Fed. Cir. 1988).

It is the Examiner’s burden to provide a reasonable explanation of why the specification does not enable the scope of the pending claims. *In re Wright*, 999 F.2d 1557, 1561-1562, 27 U.S.P.Q.2d 510, 1513 (Fed. Cir. 1993).

The following analysis of the claimed invention using the factors regarding enablement set forth in *In re Wands* illustrates that it would not require undue experimentation to practice the claimed invention.

The nature of the invention. The nature of the invention is a plasticized polymer composition with specified properties including storage modulus value, among other properties.

The state of the prior art. The state of the prior art is advanced. Biodegradable flexible films do not represent a new or completely unpredictable area of science. Furthermore, the use of lactic acid resins has been produced by chemical engineering in the past. Specification, p. 1, paragraph 5.

The relative skill in the art. The level of skill in the art is high. Thus, it would not be expected that undue experimentation would be required for a person of ordinary skill to make and use the invention as presently claimed because such a person would know a method to the film, based on the specification. A person of ordinary skill in the art would be able to read the specification and the examples in order to determine which of the listed plasticizers to use in order to achieve the properties that contained in the invention.

The predictability or unpredictability of the art. The nature of the invention is a plasticized polymer composition with specified properties including storage modulus value, among other properties. Many biodegradable plasticized polymer compositions with certain properties have been achieved in the past, for example with handling properties, adhesiveness to container, transparency, gas barrier properties. Specification, p. 1, paragraph and paragraph 8. Therefore, the nature of the art is not highly unpredictable.

The amount of direction or guidance presented. The Examiner states that the teaching of the specific kind of plasticizer used would be necessary to achieve the required properties.

Routine research, even if extended, is permissible as long as the specification provides sufficient direction or guidance to the skilled artisan. MPEP § 2164.06. Here, the specification discloses the method for obtaining the biodegradable film. Further, the specification lists various plasticizers that can be used in the invention. While the working examples do not include examples of every plasticizer listed in the specification, this is not required for enablement. The parameters provide adequate guidance for those skilled in the art to conduct reasonable, not undue, experimentation, and to readily utilize compounds in the claimed methods. Therefore, the claims are adequately enabled by the specification.

The quantity of experimentation needed. Applicant disclosed the basis of the invention, information to make the invention, and methods on how to make the invention. Applicant submits that the disclosure of this invention is more than general ideas that may or may not be workable. In contrast, the Examiner has failed to raise and substantiate a reasonable doubt of the objective truth of the statements contained in the disclosure. Therefore, the Examiner has not met the burden required to raise a proper enablement rejection. MPEP § 2164.04.

In view of the foregoing, claims 1 and 7 would not require undue experimentation and the Examiner has not yet established a prima facie case of non-enablement. As claims 2-3, 5-6 and 8-9 depend from claim 1 or 7 either directly or indirectly, these claims, too, should be allowable. Applicant respectfully requests that this rejection be withdrawn.

III. Rejections under 35. U.S.C. § 103

Claims 1-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Jun (JP 2003-012834) in view of the Examiner's statement of the skill in the art. Claim 4 has been canceled rendering the Examiner's rejection moot.

The Examiner contends that Jun discloses a biodegradable flexible film comprising (1) a poly(DL-lactic acid) where the L-isomer and D-isomer is in a proportion

between 90:10 and 85:15 and (2) a lactic acid in a 5-50% proportion to a plasticizer, wherein the value of the storage modulus at 20°C is in the range of 20-700 MPa as measured at a frequency of 10 Hz by the dynamic viscoelasticity testing method from Method A of JIS K-n m87198 and a peak value of the loss tangent ($\tan \delta$) in the range of 0.2 to 0.8.

Specifically, the Examiner states it would have been obvious to vary the content of L-lactic isomer in the polylactic acid and a plasticizer in order to achieve certain film parameters.

The invention of Claim 1 is a biodegradable wrap film comprising a lactic acid resin composition comprising a poly(DL-lactic acid) in which the proportion of L-isomer and D-isomer is 88:12 to 85:15 or 12:88 to 15:85 and a plasticizer, wherein the lactic acid resin and said plasticizer are in a proportion of 60:40 to 99:1 by mass. This resin composition has a value of the storage modulus at 40°C is in the range of 100 MPa to 3 GPa as measured at a frequency of 10 Hz and a distortion of 0.1% by the dynamic viscoelasticity testing method from Method A of JIS K-7198, a value of the storage modulus at 100°C is in the range of 30 MPa to 500 MPa, and a peak value of the loss tangent ($\tan \delta$) is in the range of 0.1 to 0.8.

Claim 7 is a biodegradable wrap film with the same proportions of L:D-isomer and lactic acid:plasticizer ratio. Additionally the resin composition of claim 7 has a value of storage modulus at 20°C is in the range of 1 GPa to 4GPa, as measured at a frequency of 10 Hz and a distortion of 0.1% by the dynamic viscoelasticity testing method from Method A of JIS K-7198, and the value of loss tangent ($\tan \delta$) at 20°C is 0.5 or less and a value of storage modulus at 40°C is in the range of 100 MPa to 800 MPa, as measured at a frequency of 10 Hz and a distortion of 0.1% by the dynamic viscoelasticity testing method from Method A of JIS K-7198.

Applicant respectfully traverses the rejection.

Applicant's newly amended claim 1 and 7 are non-obvious in view of Jun. Jun discloses a wrap film in which the value of the value of the storage modulus at 20°C is in the range of 20 - 700 MPa (Jun, claim 2). In comparison, Applicant's invention discloses a biodegradable wrap film, in which the value of storage/elasticity modulus at 20°C is in the range of 1 GPa to 4GPa. This value is much higher than the value disclosed in Jun.

While the Examiner states that it would be obvious to one skilled in the art to change the L/D ratio in a polymer and minimize the use of plasticizer in order to maximize required properties, the minimization of the plasticizer and change in L/D ratio does not explain the surprising storage modulus results. Comparative Examples 2, 3, and 4 are within the lactic acid:plasticizer ratio and D:L ratio of Applicant's invention, yet the Applicant's results in the storage modulus values are better. Comparative Example 2 and 3 shows storage modulus values at 40°C and 100°C much lower than Applicant's Examples 1 and 2.

	Storage Modulus at 20°C, 40°C, and 100°C (in MPa)	L/D Ratio	Lactic Acid: Plasticizer Ratio
Comparative Example 2	2450/350/-	88:12	10%
Comparative Example 3	1990/11/13	88:12	15%
Example 1	1990/747/88	88:12	10%
Example 2	1070/433/66	88:12	15%

Furthermore, the value of storage modulus as it is at each temperature is important in order to achieve the required results of Applicant's invention, which Jun does not achieve in its invention. (Specification, p. 2, paragraph 16).

Jun discloses a food wrap stretch film, while Applicant's invention discloses a food wrap film. While the difference is not apparent to those not familiar with the art, Jun, as a food wrap stretch film, is a different class of film wrap that requires different parameters in order to be effective for its required function. Consequently, one of ordinary skill in the art would not look to Jun when it comes to Applicant's invention, which is a food wrap film.

Finally, it would not be obvious to vary the content of L-lactic isomer in the polylactic acid and a plasticizer in order to achieve the storage modulus value of the present invention. It is not obvious how the storage modulus at 40°C and 100°C is adjusted and how the characteristic of wrap film are. Although a storage modulus can be adjusted by calibrating certain parameters, it is not obvious from such calibrations as to what value of storage modulus would be preferable in order to achieve the specific storage modulus values at the temperatures required as based on the disclosure in Jun.

Therefore, Applicant's results are not just due to an optimization of ranges and characteristics for the invention as the Examiner contends. Based on the amendments to claim 1 and the difference in storage modulus value, claims 1 and 7 of Applicant's invention are not obvious in view Jun. As claims 2-3, 5-6 and 8-9 depend from claim 1 or 7 either directly or indirectly, these claims, too, should be allowable.

IV. Rejection under 35. U.S.C. § 103

Claims 1-9 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Rosenbaum (W0/02/087877) in view of the Examiner's statement of the skill in the art. Claim 4 has been canceled rendering the Examiner's rejection moot.

The Examiner contends that Rosenbaum teaches plasticized polylactic acid film, where the content of L-lactic acid units is within the range of 80 to 100% and that D-lactic acid monomers are used to decrease the crystallinity degree. Rosenbaum further contains a layer consisting of at least one hydroxycarboxylic acid, where the copolymer is preferably built up from polymerized units of aliphatic hydroxycarboxylic acids. The Examiner states that it would be obvious to a person of ordinary skill in the art that film flexibility depends on the amount of plasticizer used as a result-effective variable.

As shown above in the arguments overcoming Jun and based on the Comparative Examples and Examples above, an optimization of the amount of plasticizer used in Applicant's invention is not what affects the surprising storage modulus results that Applicant claims. For these reasons, Applicant's invention is not obvious and claims 1 and 7 should be allowed. As claims 2-3, 5-6 and 8-9 depend from claim 1 or 7 either directly or indirectly, these claims, too, should be allowable. Lastly claim 4 has been canceled rendering the Examiner's rejection moot.

V. New Claims

Claims 10 and 11 have been added as dependent from claims 1 and 7 respectively. Both recite the plasticizer is an aliphatic dicarboxylic acid alkyl ester. Jun recites this plasticizer, but does not disclose rest of the parameters of claims 1 and 7. Rosenbaum discloses this plasticizer, but does not disclose the storage modulus values as recited in claims 1 and 7. Thus, claims 10 and 11 are allowable over the prior art at issue.

CONCLUSION

In view of the above, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

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Respectfully submitted,

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